

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

LYNN OXENBERG and
RONALD LEWIS

Plaintiffs,

v.

ALEX AZAR II, in his official capacity as the
Secretary of the Department of Health and
Human Services.

Defendant.

Case No. 2:20-cv-00738-CMR

ORDER

AND NOW, this ____ day of _____, 2020, upon consideration of Plaintiffs Lynn Oxenberg and Ronald Lewis's Motion for Summary Judgment, and any response thereto, it is hereby **ORDERED** that the Motion is **GRANTED**, and summary judgment is hereby entered in favor of Plaintiffs.

Pursuant to 42 U.S.C. § 405(g) (fourth sentence), this case is remanded to the Secretary with instruction to provide coverage for Plaintiffs' claims.

BY THE COURT:

The Honorable Cynthia M. Rufe
United States District Judge

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PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Plaintiffs Lynn Oxenberg and Ronald Lewis (collectively, "Plaintiffs"), by and through its undersigned counsel, hereby move this Court for an order granting Plaintiffs' Motion for Summary Judgment pursuant to Federal Rule of Civil Procedure 56. In support of this Motion, Plaintiffs incorporate the within Memorandum of Law, Supporting Declaration, and exhibits attached thereto.

Dated: March 30, 2020

Respectfully submitted,

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**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT
OF THEIR MOTION FOR SUMMARY JUDGMENT**

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Pursuant to the Court's Order of March 11, 2020, and FED.R.CIV.P. 56, Plaintiffs Lynn Oxenberg and Ronald Lewis (collectively, Plaintiffs) respectfully file this motion for summary judgment that the Secretary is barred by collateral estoppel from denying Ms. Oxenberg' and Mr. Lewis' claims for Medicare coverage, as a matter of law, and that the coverage denials at issue in this case should be reversed.

I. INTRODUCTION

This is an administrative review case, the resolution of which turns solely on an issue of law. As detailed in the Complaint and below, Ms. Oxenberg and Mr. Lewis are suffering from a particularly lethal form of brain cancer (glioblastoma multiforme (GBM)). Even with tumor treatment field therapy (TTFT), the two-year survival rate remains well below 50%.

Ms. Oxenberg and Mr. Lewis have repeatedly litigated the issue of whether TTFT is "medically reasonable and necessary" for them and a covered Medicare benefit. Both Ms. Oxenberg and Mr. Lewis have prior decisions from ALJs finding in their favor on these issues. The Secretary did not appeal those decisions and they have now become final. Nevertheless, the Secretary continues to force Ms. Oxenberg and Mr. Lewis to re-litigate the identical issues during the time they should be spending with family and focusing on their recovery.

This has to stop.

II. LEGAL BACKGROUND

Collateral estoppel (*i.e.*, "issue preclusion") is a venerable common law doctrine that bars re-litigation of a legal or fact issue determined in a prior proceeding. Under the doctrine of collateral estoppel, "once an issue is actually and necessarily determined by a court of competent jurisdiction, that determination is conclusive in subsequent suits based on a different cause of action involving a party to the prior litigation." *Montana v. United States*, 440 U.S. 147, 153-54

(1979). Collateral estoppel applies if: 1) the issue sought to be precluded is the same as that involved in the prior action; 2) that issue was actually litigated; 3) it was determined by a final and valid judgment; and 4) the determination was essential to the prior judgment. *See, e.g., Anderson v. C.I.R.*, 698 F.3d 160, 164 (3d Cir. 2012). As shown herein, each of those requirements is clearly satisfied here.

Parallel/concurrent litigation is common. Where there is parallel/concurrent litigation, whichever case reaches finality first may have preclusive effect on the other. *See, e.g., Kline v. Burke Const. Co.*, 260 U.S. 226, 230 (1922); *Adkins v. Nestle Purina Petcare Co.*, 779 F.3d 481, 484 (7th Cir. 2015) (“The first to reach final decision can affect the other ... through rules of claim and issue preclusion (res judicate and collateral estoppel)[.]”). In other words, a later-filed case that reaches finality first may have preclusive effect on an earlier-filed, but still on-going litigation.

Because of the unique posture of the United States as a litigant, the Supreme Court has held that offensive, non-mutual collateral estoppel does not apply against the United States. *See U.S. v. Mendoza*, 464 U.S. 154 (1984). As a result, only a party to a prior proceeding with the government can assert collateral estoppel against the government. Here, Ms. Oxenberg and Mr. Lewis are not seeking to collaterally estop the Secretary with respect to coverage for TTFT claims filed by any person other than themselves. Instead, Mrs. Oxenberg and Mr. Lewis contend that they should not have to relitigate the same coverage issues against the Secretary that have already been finally and conclusively determined in their favor.

Proceedings giving rise to collateral estoppel are not limited to cases before federal or state courts. In *Astoria Federal Savings & Loan Assoc. v. Solimino*, 501 U.S. 104, 107-8 (1991), the Supreme Court held:

We have long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of

administrative bodies that have attained finality. When an administrative agency is acting in a judicial capacity and resolves dispute issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply *res judicata* to enforce repose. Such repose is justified on the sound and obvious principle of judicial policy that a losing litigant deserves no rematch after a defeat fairly suffered, in adversarial proceedings, on an issue identical in substance to the one he subsequently seeks to raise. To hold otherwise would, as a general matter, impose unjustifiably upon those who have already shouldered their burdens, and drain the resources of an adjudicatory system with disputes resisting resolution. The principle holds true when a court has resolved an issue, and should do so equally when the issue has been decided by an administrative agency, be it state or federal, which acts in a judicial capacity.

(internal citations omitted); *see also B & B Hardware, Inc. v. Hargis Indus., Inc.*, 135 S.Ct. 1293, 1302-3 (2015) (confirming that administrative decisions can be a basis for issue preclusion). The application of collateral estoppel based on agency determinations (even against agencies) has been affirmed in numerous cases. *See, e.g., Brewster v. Barnhart*, 145 Fed.App'x. 542 (6th Cir. 2005) (SSA ALJ collaterally estopped by prior ALJ' work determination); *Islam v. U.S. D.H.S.*, 136 F.Supp.3d 1088 (N.D. Cal. 2015) (D.H.S. collaterally estopped by prior immigration judge's determination).

III. FACTUAL BACKGROUND

A. Tumor Treatment Field Therapy (TTFT)

Glioblastoma multiforme (GBM) is an unusually deadly type of brain cancer. Without treatment, survival is typically 3 months. With earlier forms of treatment before TTFT, the survival rate at two years after treatment is ~31%, while at five years, only ~5% of patients are living.

More recently, treating GBM using alternating electric fields has been developed. This is known as tumor treatment field therapy (TTFT). Alternating electric fields interfere with tumor cell replication and have been shown to dramatically increase the period during which the GBM

does not progress, as well as overall survival rates. Indeed, TTFT has proven so effective that, in late 2014, a randomized clinical trial of TTFT was suspended because it would have been unethical to withhold TTFT treatment from the control group.¹

In ground-breaking papers published in the Journal of the American Medical Association (JAMA)² in 2015 and 2017, TTFT was shown to increase the 2-year survival rate by more than 38% and to nearly triple the five-year survival rate.³

As reported, TTFT was the first significant advance in treating GBM in more than a decade. TTFT has become the standard of care for treating GBM and essentially all major private insurers cover TTFT. TTFT extends GBM patients' lives, in some cases, by years. Between January 2016 and December 2018, at least 93 scientific papers were published demonstrating the effectiveness of TTFT. It has a level one recommendation in the National Comprehensive Cancer Network

¹ In much scientific research, study participants are randomly assigned to “control” and “test” groups. The “control” group does not receive the treatment being tested. In contrast, the “test” group does. Proceeding in this way facilitates the determination of which effects, if any, are the result of the tested treatment as opposed to normal variation among the study participants. During the course of a study, interim results are frequently measured to determine whether the study is proceeding as planned and whether any changes are needed. When the interim results indicate that the tested treatment has a significant effect on health or safety, either negative or positive, ethical guidelines dictate that the study should be halted. Thus, if the interim results indicate that the tested treatment was significantly more likely to result in death than the control group, the study would be halted and the treatment no longer given to the “test” group. Likewise, if the interim result indicated that the tested treatment was life-saving, the study would be halted and the treatment would be made available to the “control” group. In those circumstances, withholding the treatment from the “control” group would be unethical.

² JAMA is widely regarded as one of the most prestigious medical journals in the United States and the world.

³ See Stupp, *et al.*, “MAINTENANCE THERAPY WITH TUMOR-TREATING FIELDS PLUS TEMOZOLOMIDE VS. TEMOZOLOMIDE ALONE FOR GLIOBLASTOMA: A RANDOMIZED CLINICAL TRIAL”, JAMA, Vol. 314, No. 23, pgs. 2535-43 (Dec. 15, 2015); Stupp, *et al.*, “EFFECT OF TUMOR TREATING FIELDS PLUS MAINTENANCE TEMOZOLOMIDE VS. MAINTENANCE TEMOZOLOMIDE ALONE ON SURVIVAL IN PATIENTS WITH GLIOBLASTOMA”, JAMA, Vol. 318, No. 23, pgs. 2306-2316 (Dec.19, 2017).

(NCCN) guidelines, *i.e.*, there is consensus, among the experts, based on a high level of evidence, that TTFT is a recommended intervention. Further, TTFT is FDA approved.

The sole supplier of the equipment that delivers TTFT is Novocure, Inc., which manufactures the Optune system. The Optune system is rented on a monthly basis. Once a Medicare patient suffering from GBM is prescribed the Optune system, they will have monthly claims for Medicare coverage. Sadly, there is no known cure for GBM and patients prescribed TTFT treatment will have to continue that treatment for the rest of their lives.

B. The Medicare Appeals Process

People suffering from GBM and being treated with TTFT will have multiple claims for Medicare coverage. Typically, these claims will be submitted every one to three months to reflect their continued usage of the TTFT device. Each claim for Medicare coverage concerns only the one to three months at issue for that claim.

Claims submitted by beneficiaries enrolled in Original Medicare are subject to a five (5) level appeal process that can (and typically does) take more than a year. At issue at each stage of the process is whether the claim is a Medicare covered benefit/is medically reasonable and necessary for the beneficiary. The beneficiary begins by submitting a claim. *See* 42 C.F.R. §§ 405.920-928. If the claim is denied, the beneficiary can request “redetermination.” *See* 42 C.F.R. §§ 405.940-958. If the claim is still denied, the beneficiary can request “reconsideration.” *See* 42 C.F.R. §§ 405.960-978. If the claim is still denied, the beneficiary can appeal to an administrative law judge (ALJ). *See* 42 C.F.R. §§ 405.1000-1058.

The Secretary may choose to participate in the hearing held by the ALJ. *See* 42 C.F.R. § 405.1010. If the ALJ denies the claim, the beneficiary can appeal to the Medicare Appeals Council

(Council). *See* 42 C.F.R. §§ 405.1100-1140. Finally, if the claim is still denied, the beneficiary can file suit in district court. *See* 42 U.S.C. §§ 405(g) and 1395ff(b).

Although the statutes and regulations require both ALJs and the Council to issue decisions within 90 days, those deadlines are routinely missed. *See, e.g.*, 42 U.S.C. § 1395ff(d)(2). Thus, Medicare beneficiaries seeking coverage are often thrown into a multi-year effort to obtain coverage or at least get a decision on each denied claim before they can seek relief in a federal court.

C. Mrs. Oxenberg

Lynn Oxenberg is a 69-year old resident of Elkins Park, wife of 49 years to husband Larry, mother of two, and grandmother to four. Prior to her diagnosis with GBM in November 2017, Mrs. Oxenberg held several management roles with a newspaper group in the New York area and participated in a number of activities, including volunteering with a women's group (Hadassah) at her synagogue. After surgery and chemo-radiation, Mrs. Oxenberg was prescribed the Optune TTFT device.

Strafuss' June 3, 2019 Decision Granting Coverage:

On June 3, 2019, ALJ Thomas Strafuss issued a decision favorable to Mrs. Oxenberg in ALJ Appeal No. 1-8452468241 for Mrs. Oxenberg's claim for the months of July-October 2018. A copy of that decision is attached as Exhibit A to the Declaration of James C. Pistorino ("Pistorino Declaration"). Judge Strafuss found:

- 1) "the 2018 National Comprehensive Cancer Network ("NCCN") Guidelines allow for alternating use of electric field therapy with Temozolomide when treating glioblastoma." (Decision at 5);
- 2) "the tumor treatment field therapy was medically reasonable and necessary in this case." (Decision at 6).

- 3) “Medicare coverage is available for the tumor treatment field therapy requested by the Enrollee.” (Decision at 6);
- 4) “The services requested are covered under Medicare Part B and thus Medicare coverage must be approved.” (Decision at 6); and
- 5) “Medicare Part B coverage does exist for electrical stimulation for cancer treatment (E0766, tumor treatment field therapy)” (Decision at 6).

The Secretary did not appeal Judge Strafass’ decision and it has become final.

Cohn-Morros’ September 5, 2019 Decision Granting Coverage:

On September 5, 2019, ALJ Carolyn Cohn-Morros issued a decision favorable to Mrs. Oxenberg in ALJ Appeal No. 1-8651098761 for Mrs. Oxenberg’s claim for the months of November 2018-January 2019. A copy of that decision is attached as Exhibit B to the Pistorino Declaration. Judge Cohn-Morros found:

- 1) “the TTFT device was medically reasonable and necessary for [Mrs. Oxenberg] and Medicare coverage shall be allowed.” (Decision at 10);
- 2) “The medical literature is overwhelming in establishing the medical reasonableness and necessity for this device for [Mrs. Oxenberg].” (Decision at 11);
- 3) “the medical reasonableness and necessity for using such a device to treat [Mrs. Oxenberg’s] condition was clearly warranted.” (Decision at 11); and
- 4) “[Mrs. Oxenberg] is entitled to coverage for the TTFT (E0766) provided on the dates of service. This device was medically reasonable and necessary pursuant to the FDA research and guidelines, the overwhelming data submitted by [Mrs. Oxenberg] and Section 1862(a)(1) of the Social Security Act.” (Decision at 12).

The Secretary did not appeal Judge Cohn-Morros’ decision and it has become final.

Cohn-Morros’ October 24, 2019 Decision Granting Coverage:

On October 24, 2019, ALJ Carolyn Cohn-Morros issued a favorable decision to Mrs. Oxenberg in ALJ Appeal No. 3-8686737644 for Mrs. Oxenberg’s claim for the months of February-May 2019. A copy of that decision is attached as Exhibit C to the Pistorino Declaration. Judge Cohn-Morros found:

- 1) “the TTFT device was medically reasonable and necessary for [Mrs. Oxenberg] and Medicare coverage shall be allowed.” (Decision at 7);
- 2) “[t]he medical literature is overwhelming in establishing the medical reasonableness and necessity of [TTFT] for [Mrs. Oxenberg].” (Decision at 8);
- 3) “the TTFT device was medically reasonable and necessary, is currently the best treatment for [Mrs. Oxenberg’s] condition and shall be covered pursuant to the provisions of Section 1682(a)(1) of the Social Security Act.” (Decision at 9); and
- 4) “[TTFT] was medically necessary pursuant to the FDA research and guidelines, the overwhelming medical data submitted by [Mrs. Oxenberg], and Section 1862(a)(1) of the Social Security Act. Medicare payment shall be allowed on the TTFT device.” (Decision at 9).

The Secretary did not appeal Judge Cohn-Morros’ decision and it has become final.

MacDougall’ September 5, 2019 Decision Denying Coverage:

Nevertheless, on September 5, 2019 (*i.e.*, the same day Mrs. Oxenberg received a favorable determination from ALJ Cohn-Morros), ALJ Bruce MacDougall issued a decision in ALJ Appeal No. 1-8393258352 finding that TTFT was not medically reasonable and necessary and, therefore, not covered for the months April-June 2018. *See* Decision at 7 (“... the services here are not reasonable and necessary and there is no coverage for the TTFT to treat [Ms. Oxenberg’s] glioblastoma multiforme.”). A copy of that decision is attached as Exhibit D to the Pistorino Declaration.

Mrs. Oxenberg timely appealed. Pursuant to 42 U.S.C. § 1395ff(d)(2), the Council was required to issue a ruling within 90 days. When no decision was received by that date, Mrs. Oxenberg requested “escalation” pursuant to 42 C.F.R. § 405.1132 bringing the three favorable decisions as well as authority on collateral estoppel from the Supreme Court to the Council’s attention. A copy of Mrs. Oxenberg’s requested escalation is attached as Exhibit E to the Pistorino Declaration. Subsequently, the Council did not issue a decision, which authorized the filing of this suit in district court.

D. Mr. Lewis

Ronald Lewis is a 69-year old, life-long resident of the Doylestown area, husband of more than 40 years to wife Virginia, father of two, and grandfather to four. Prior to his diagnosis with GBM in early 2018, Mr. Lewis was employed as an electrical engineer, designer, and analyst working on contracts for the Naval Surface Warfare Center in Philadelphia. After surgery and chemo-radiation, Mr. Lewis was prescribed the Optune TTFT device.

Hynum’ October 24, 2019 Decision Granting Coverage:

On October 24, 2019, ALJ Gerald Hynum issued a decision favorable to Mr. Lewis in ALJ Appeal No. 3-8693279102 for Mr. Lewis’ claim for the months of November 2018-May 2019. A copy of that decision is attached as Exhibit F to the Pistorino Declaration. Judge Hynum found:

- 1) “that the tumor treatment field therapy for treatment of [Mr. Lewis’] glioblastoma for the dates of service was medically reasonable and necessary.” (Decision at 3); and
- 2) “the Optune (TTFT) system has been shown to be safe and effective, and it was and is medically necessary for the treatment of [Mr. Lewis’] newly discovered glioblastoma and Medicare coverage requirements have been met for the dates of service at issue.” (Decision at 4).

The Secretary did not appeal Judge Hynum’s decision and it has become final.

Levine May 30, 2019 Decision Denying Coverage:

Nevertheless, on May 30, 2019, concerning claims for the months of July-October 2018, ALJ Pamela Levine issued a decision in ALJ Appeal No.1-8411344383 denying coverage. Decision at 5 (“Because TTFT is categorized as not reasonable and necessary, payment cannot be made under the durable medical equipment benefit ...”). A copy of that decision is attached as Exhibit G to the Pistorino Declaration. Mr. Lewis timely appealed. Again, when no decision was received within 90 days, Mr. Lewis requested escalation, and brought the favorable decision to the Council’s attention as well as authority from the Supreme Court. A copy of Mr. Lewis’ requested

escalation is attached as Exhibit H to the Pistorino Declaration. Subsequently, the Council did not issue a decision, which authorized the filing of this suit in district court.

IV. DISCUSSION

As a result of the separate, final, and non-appealable decisions finding TTFT to be “medically reasonable and necessary” and a covered benefit for Ms. Oxenberg and Mr. Lewis, the Secretary should be collaterally estopped from issuing denials on the same grounds that were rejected by those other final decisions. Pursuant to 42 U.S.C. § 405(g) (fourth sentence), the Court should reverse the Secretary’s denials, order coverage, and remand these cases with instructions to the Secretary to effectuate the Court’s decision.

A. Collateral Estoppel

Collateral estoppel should conclusively bar the Secretary from relitigating the issue of TTFT coverage for Ms. Oxenberg and Mr. Lewis.

1. The Issue Sought to be Precluded is the Same as That Involved in the Prior Action

Pursuant to 42 U.S.C. § 1395y(a)(1)(A), any item which is not “medically reasonable and necessary” is excluded from coverage. Thus, whenever a coverage decision has finally determined that a device/service is a Medicare covered benefit, it has necessarily determined that the device/service is medically reasonable and necessary for that particular beneficiary.

In the present case, Plaintiffs seek to preclude the Secretary from continuing to litigate, dispute, or deny that TTFT is a Medicare-covered benefit (and the subissue of whether TTFT is “medically reasonable and necessary”) for Ms. Oxenberg and Mr. Lewis.

As noted above, in one or more final decisions on separate claims brought by the same plaintiff, the ALJ decided the exact same issue of whether TTFT was a Medicare covered benefit

(and the subissue of whether it is “medically reasonable and necessary”). For Ms. Oxenberg, that issue was disputed in Judge Strafuss’ and both of Judge Cohn-Morros’ final decisions granting coverage and was again litigated in Judge MacDougall’s decision denying coverage. For Mr. Lewis, that issue was disputed in Judge Hynum’s final decision granting coverage and was again litigated in Judge Levine’s decision denying coverage.

Likewise, in the decisions denying coverage at issue here, the same issue was presented and necessarily decide in the exactly opposite way. *See* MacDougall’ Decision at 7 (“... the services here are not reasonable and necessary and there is no coverage for the TTFT to treat [Ms. Oxenberg’s] glioblastoma multiforme.”); Levine’ Decision at 2 (“Whether the TTFT ... met Medicare coverage criteria. ... Whether the services are medically reasonable and necessary in accordance with § 1862(a)(1)(A) ... and are reimbursable under Medicare.”); at 5 (“Because TTFT is categorized as not reasonable and necessary, payment cannot be made under the durable medical equipment benefit ...”).

Thus, in all TTFT claims brought by Ms. Oxenberg and Mr. Lewis, the same determinative issues were presented, and each Plaintiff has a final decision on those issues in his or her favor.

2. The Issue Was Actually Litigated in the Prior Proceedings

As detailed above, the issue of whether TTFT was a Medicare-covered benefit/was “medically reasonable and necessary” for each of the Plaintiffs was actually litigated in each of the prior favorable cases.

3. The Issue Was Determined by a Valid and Final Judgment

Of course, the favorable ALJ decisions being invoked for collateral estoppel are final decisions by ALJs within the jurisdiction of the Secretary’s Department itself. Thus, the validity of the judgments is beyond dispute. “A judgment is ‘valid’ when it has been rendered by a court

of competent subject matter jurisdiction and the party against whom judgment is rendered either has submitted to the jurisdiction of the court or has been afforded adequate notice.” *See O’Leary v. Liberty Mutual Ins. Co.*, 923 F.2d 1052, 1066 (3d Cir. 1991).

Likewise, that the Secretary did not appeal the adverse ALJ judgments and the fact that they have become final is also beyond dispute. *See* 70 Fed.Reg. 36386-7 (June 23, 2005) (“The ALJs within the Office of Medicare Hearings and Appeals issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council[.]”); 42 C.F.R. § 405.1102 (“... a written request for a Council review within 60 calendar days ...”); *see also Smith v. Berryhill*, 139 S.Ct. 1765, 1775-6 (2019) (under APA, action is “final” if it: 1) marks the consummation of the agency’s decision making process; and 2) is one by which rights have been determined or from which legal consequences will flow). Thus, the third factor for collateral estoppel is fully established for each plaintiff.

4. The Determination Was Essential to the Prior Judgment

As detailed above, whether Medicare coverage is available for TTFT used to treat the GBM of Ms. Oxenberg and Mr. Lewis is the very question to be determined in every claim brought by Plaintiffs. Further, as detailed above, essential to the prior, final judgments was a determination that TTFT was “medically reasonable and necessary.”

The fact that, in some cases, the favorable ALJ decision giving rise to collateral estoppel occurred after the unfavorable ALJ decision at issue here is of no moment. As indicated, whichever decision reaches finality first may give rise to collateral estoppel against an earlier, but still on-going, litigation. *See, e.g., Rashid v. Hazleton*, 1996 WL 114809 at *4 (E.D.P.A. March 14, 1996). Once the Secretary elected to allow the favorable decisions for Ms. Oxenberg and Mr.

Lewis to become final, he should be estopped from continuing to litigate that same issue in all pending and future claims by the same Plaintiffs.

Accordingly, the Secretary should be estopped from denying that TTFT is a Medicare covered benefit for Ms. Oxenberg and Mr. Lewis (as well as the subissue of whether TTFT is “medically reasonable and necessary”) to treat their GBM conditions.

B. The Decisions At Issue Should Be Reversed and Coverage Ordered

Once this Court properly applies collateral estoppel against the Secretary with respect to the issue of whether TTFT is a covered benefit/is “medically reasonable and necessary” for Plaintiffs, the decisions at issue should be reversed. Each of the decisions denying coverage was premised solely on the conclusion that TTFT was not “medically reasonable and necessary” for each of the Plaintiffs. That is, there was no other basis for the denial of coverage (*e.g.*, the beneficiary passed away). Thus, if the Secretary is collaterally estopped from re-litigating that issue, then there is no reason that coverage can/should be denied.

Pursuant to 42 U.S.C. § 405(g) (fourth sentence), this Court can modify or reverse the Secretary’s decisions “with or without remanding the cause for a rehearing.” If the Secretary is collaterally estopped from denying coverage to Plaintiffs in Appeal No. 1-8393258352 (for Ms. Oxenberg) and Appeal No. 1-8411344383 (for Mr. Lewis), then there is no need or reason for further review by the Secretary and coverage should be ordered.

C. Response to the Secretary’s Comments Regarding Coverage and Financial Responsibility

During the two conferences held so far in this matter, the Secretary has sought to emphasize: 1) that Ms. Oxenberg and Mr. Lewis are continuing to receive the TTFT treatment for which the Secretary has denied coverage; and 2) that Ms. Oxenberg and Mr. Lewis will not be financially responsible for the cost of their GBM care. These comments reflect a shockingly

cavalier attitude to the lives of Ms. Oxenberg and Mr. Lewis that is unbecoming of their government.

None of Ms. Oxenberg' or Mr. Lewis' claims for coverage for the life-extending TTFT has been approved in six months. In the Secretary's view, Medicare's denial of coverage is no problem because the third party supplier will continue to provide their TTFT treatment at its own expense. That is, the Secretary is confident that a third-party, with no duty to Ms. Oxenberg or Mr. Lewis, will continue to provide treatment without payment because failing to do so would be immoral – all while the Secretary himself continues to do the same. That position is less than admirable.

With regard to financial liability, the Secretary is referring to portions of the coverage denials at issue that contend that the supplier is responsible for paying for Ms. Oxenberg' and Mr. Lewis' TTFT care because the supplier should have known “that the disputed services were not medically reasonable and necessary.” *See* MacDougall Decision at 7. Even if the supplier did not know that when supplying the treatment at issue in this case, the supplier will know that is the Secretary's position when treatment is requested in the future. Ms. Oxenberg and Mr. Lewis will continue to need TTFT treatment for the rest of their lives. Given the Secretary's position, Ms. Oxenberg and Mr. Lewis have a reasonable fear that their treatment may be discontinued because of non-payment. What does the Secretary think will happen when Ms. Oxenberg and Mr. Lewis seek treatment in April, May, June, etc.?

The Secretary is displaying a callous and cavalier attitude to the already difficult lives of Ms. Oxenberg and Mr. Lewis. Ms. Oxenberg and Mr. Lewis should be concentrating on their recovery and spending time with their loved ones, not engaging in repetitive litigation while the Secretary devises new procedural ways to delay resolution of TTFT claims or more baseless grounds for rejecting meritorious claims for coverage.

V. CONCLUSION

The Secretary should be collaterally estopped from denying that TTFT is medically reasonable and necessary and a covered Medicare benefit for Mrs. Oxenberg and Mr. Lewis. The decisions at issue in this case should be reversed and coverage of Ms. Oxenberg and Mr. Lewis' claims ordered.

Dated: March 30, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, hereby certify that on this 30th day of March, 2020, I electronically filed the foregoing Motion for Summary Judgment and supporting papers with the Clerk of Court using the CM/ECF system as follows:

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